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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/211,755 12/15/98 JONES

K 54002-D/JPW/

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HM12/1030

EXAMINER

BRANNOCK, M

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

10/30/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/211,755

Applicant(s)

Jones, KA

Examiner

Michael Brannock, Ph.D.

Group Art Unit

1646



☒ Responsive to communication(s) filed on Aug 21, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 190-249 is/are pending in the application

Of the above, claim(s) 190-207, 209, 211, 212, 215-220, 226, 227, 232, and 241 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 208, 210, 213, 214, 221-225, 228-231, and 233-240 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 190-249 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Status of Application: Claims and Amendments***

1. Claims 190-249 are pending.
2. Claims 208, 210, 213, 214, 221-225, 228-231, and 233-240, as the claims relate to methods of screening for an agonist of a GABA<sub>B</sub>R1/R2 receptor, are currently under examination.
3. Applicant is notified that the amendments put forth in Paper 13, 8/25/00, have been entered in full.

### ***Response to Amendment***

#### **Withdrawn Objections/Rejections:**

4. The objection to the specification, as put forth in item 5 of Paper 12 (5/24/00) is withdrawn in view of Applicants amendments.
5. Applicant is notified that the application is now in compliance with the rules regarding sequence disclosures, as put forth in item 7 of Paper 12.
6. The rejection of claim 233 and 235 under 35 USC 112, first paragraph, as put forth in item 9 of paper 12 is withdrawn in view of Applicant's compliance with the criteria set forth in 37 C.F.R. §§ 1.801-1.809, documentation being provided in Paper 13. However, as was put forth in item 9 of paper 12, claims 233 and 235 remain subject to the same scope of enablement rejection put forth below regarding amino acid sequence variants of a GABA<sub>B</sub>R1 polypeptide.

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**Maintained Rejections:**

7. Claims 208, 210, 213, 214, 221-225, 228-231, 234, 236-240 stand rejected under 35 U.S.C. 112, first paragraph, as put forth Paper 12 (item 8): because the specification, while being enabling for a method of identifying agonists of the GABA<sub>B</sub>R1/R2 receptor wherein the GABA<sub>B</sub>R1 receptor is either of the splice variants disclosed by Kaupmann *et al.*, *Nature* 386(239-246)1998, referred to in the specification on page 4, and wherein the GABA<sub>B</sub>R2 receptor is either of the polypeptides disclosed in the instant application as SEQ ID NO: 2, 4, or 47, or a polypeptide having an amino acid sequence identical to that encoded by the plasmid deposited as ATCC Accession No. 209104 or 203515, does not reasonably provide enablement for a method of identifying agonists of the GABA<sub>B</sub>R1/R2 receptor wherein the receptor GABA<sub>B</sub>R1/R2 comprises polypeptides other than those recited above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Regarding enablement for GABA<sub>B</sub>R1 receptor polypeptides, Applicant argues that the rejection is unduly narrow, in that GABA<sub>B</sub>R1 receptor polypeptides other than those disclosed by Kaupmann *et al.* could be used. Applicant urges that the polypeptides disclosed by White *et al.* (*Nature* 396(679-682)1998), referenced in the IDS, could also be used. This argument has been fully considered but not deemed persuasive because the White *et al.* polypeptides are not taught in the instant specification: the White *et al.* polypeptides were disclosed in a *Nature* article which had an issue date two days after the filing date of the of the instant application. Thus, using the

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specification as a guide, one of skill in the art would not have been able to use the White et al. polypeptides.

Further, the claims were originally rejected because the claims encompassed amino acid sequence variants yet the specification failed to teach how to make amino acid sequence variants that preserved the properties of the GABA<sub>B</sub>R1/R2 receptor (see pages 6-8 of Paper 12). Further, claims 208, 213, 224, and 231 have been amended to specifically require these variants, i.e., that the GABA<sub>B</sub>R2 polypeptide include amino acid sequence variations which do not change the properties of the GABA<sub>B</sub>R2. Applicant's arguments in Paper 13 do not appear to include any discussion of this critical part of the rejection.

Thus, for the reasons put forth in item 8 of Paper 12, it would require undue experimentation on the part of any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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*Conclusion*

8. No claims are allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Paul Rameo*  
*Primary Examiner*

MB



October 24, 2000